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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,777	11/26/2003	Robert J. Marshall	PRL-101	7232

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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/722,777	MARSHALL, ROBERT J.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) *13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12, 20-22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This Office Action is in response to the Applicant's reply received 7/02/10. Claims 4-22 and 24-26 are pending. Claims 13-19 are withdrawn. Claims 1-3, 23 and 27-38 are cancelled. Claims 4, 13, 16, 21, 24 and 26 have been amended. No Claims are new. 4-12, 20-22 and 24-26 are considered in this Office Action.

Response to Applicant's Arguments

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of remaining claims 4-10, 20-22, and 25-26 over Hastings et al. in view of Niggemann, Biewenga et al. and in further of Hermann et al. in light of support by Dunne et al. and Mercenier et al. were considered but not found persuasive.

Claims 4-10, 20-22, and 25-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent # 6368617, April 9, 2002) in view of Niggemann (DE 19730538, 1999), Biewenga et al. (Gen. Pharmac, 1997) and in further of Hermann et al. (Euro. J. Pharm Sci, 1996) in light of support by Dunne et al. and Mercenier et al.

These amended claims are to a composition comprising the following:

- A least one probiotic organism
- R-lipoic acid
- One nutritive agent
- DHLA
- An effective amount of a probiotic activity halting agent to halt probiotic activity in the composition such as ethanol

The last limitation "an effective amount of a probiotic activity halting agent to halt probiotic activity in the composition" when interpreted broadly reads on any amount of such an agent. The Applicant appears to construe the claim to mean that the while the probiotic activity is halted the organism is still live and vital. However this is the not the case. The Examiner searched the Specification for guidance as to the "effective amount" and did not readily find a number or formula explicitly defining what is an "effective amount" of agent. Therefore when this limitation is given it broadest, reasonable interpretation an agent in any amount will read as "halting probiotic activity" whether the actual amount may be far larger or smaller and the degree or duration of probiotic activity halted is infinitesimally small.

The probiotic organism can be from *Lactobacillus*, *Bifidobacterium*, *Enterococcus*, *Streptococcus thermophilus*. More specifically the microorganisms can be selected from the group consisting of: *L. acidophilus, L. paracasei, L. fermentum, L. rhamnosus, L. johnsonii, L. plantarum, L. reuteri, L. salivarius, L. brevis, L. bulgaricus, L. helveticus, L. grasseri, L. casei, L. lactis, B. bifidum, B. breve, B. infantis, B. longum, B. lactis, E. faecium,* and *E. faecalis*.

Claim 21 is an additional composition comprising *B. longum, L. acidophilus, E. faecium, Streptococcus thermophilus* and R-Lipoic acid, DHLA and at least one nutritive agent. Claim 22 depends from claim 21 and further comprises *B. breve, B. infantis, L. casei, L. fermentum, L. helveticus, and L. plantarum.*

Hastings et al. teach a composition in claim 11 (col 7) comprising a probiotic blend of *B. bifidum* and *L. acidophilus*, a nutrient substance such as omega-3 fatty acids and saccharides, and can further comprise alpha-lipoic acid as an antioxidant (claim 15, col 8). This composition can be formulated into a liquid broth (Example 1). While Hastings does not teach solely the (R)

enantiomer of lipoic acid, it is obvious to use this enantiomer from the teachings of Hermann et al.

Herman et al. teach that of the racemic forms of alpha lipoic acid, the (R) enantiomer has greater bioavailability than the (S) enantiomer (Abstract, last 3 lines). One of ordinary skill in the art that knew of the teachings of Hermann et al. would recognize using the enantiomerically pure (R) form of lipoic acid would improve the composition of Hastings et al. The motivation is provided by Hastings et al. who show that the bioavailability of R-lipoic acid is superior to S-lipoic acid. The reasonable expectation of success is provided by Hastings et al. who show that the composition which already includes R-lipoic in a racemic mix with S-lipoic acid can be formulated.

While it would be obvious to use R-lipoic acid as antioxidant, Hastings et al. does not teach adding DHLA, which is the reduced form of R-lipoic acid. However this would be obvious to one of ordinary skill in the art in view of the teachings of Biewenga et al. They teach that DHLA and lipoic acid are both antioxidants and that DHLA even has more antioxidant properties than lipoic acid (Biewenga, See Abstract). Therefore Biewenga et al. establishes DHLA and lipoic acid as art recognized equivalents for the same purpose and as such it would be obvious to combine the two in the same composition (M.P.E.P. § 2144.06 I)

Hastings et al. also does not teach a composition containing all the bacteria listed in claims 21 or 22. However these bacteria are well known in the art as probiotic bacteria as supported by Mercenier et al. (Current Pharm. Design Jan. 2003) and Dunne et al. (Antonie van Leeuwenhoek, 1999). Hastings et al. already uses a probiotic blend of *B. bifidum* and *L. acidophilus*. According to M.P.E.P. § 2144.06:

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Since Hastings et al. already adds a probiotic blend to their composition it would be *prima facia* obvious to add other probiotic organisms to their invention.

Hastings et al. does not teach adding an agent that halts probiotic activity such as ethanol. However this would be obvious in view of Niggemann. They teach that small amounts of ethanol are frequently added to other probiotic compositions such as kefir and kombucha (Niggemann, pg 3 of translation). They teach that these small amounts of ethanol increase the shelf life of probiotic products (Niggemann, pg 2 of translation). Niggemann also teaches that while their composition has ethanol, the amount of ethanol is in very small (Niggemann, pg 4 of translation, middle). Even with this small amount of ethanol Niggemann teaches that their composition still has active microorganisms (Niggemann, pg 4 of translation, middle and Examples 1 and 2). Niggemann et al. even teaches that these probiotic compositions are beneficial to the intestine (Niggemann, pg 1 of translation, bottom) like those of Hastings et al. It would be obvious for one of ordinary skill in the art to apply the teachings of Niggemann to those of Hastings since Niggemann expressly teach that small amounts of ethanol improve the shelf life of probiotic products and are still beneficial to the intestine. This would simply be a matter of using a known technique to improve other probiotic compositions ((KSR Int'l Co. v. Teleflex, Inc. 550 U.S. 398 (2007), pg 13).

Therefore claims 4-10, 20-22, 25-27, and 29-35 remain obvious in view of the above references.

The Applicant argues that Niggemann teaches away from the composition by disclosing high levels of ethanol that is undesirable due to small, flavor and unsuitability for infants and children. The Applicant also argues that such an addition of ethanol kill any microorganism in the composition, thus negating the purpose of the inventions of Biewenga et al. and Hermann et al. Indeed while Niggemann does disclose this, it is in the context of a problem in the art that is fixed by their invention. Niggemann discloses that 0.1 to 1.5 vol% of ethanol is considered significant and has undesirable effects. They fix this by making compositions by limiting the ethanol content to 0.04 vol% (Examples 1 and 5) or 0.06% (Examples 2 and 3) in their probiotic compositions. Indeed Example 3 shows that these small ethanol contents increase the shelf life to at least 3 weeks and a week after opening if refrigerated (Translation, pg 6, last 2 lines). The table in Example 3 shows the active microorganisms present in the composition. Therefore Niggemann teaches that small amounts of ethanol improve shelf life and still maintain the viability of probiotic microorganisms and thus the therapeutic value of their compositions. Therefore the Examiner cannot conclude that adding small amounts of ethanol teaches away from the cited references since the probiotic therapeutic value remains intact and activity is halted as evidenced by greater long term viability.

In this regard, Applicant appears to equate "halting activity" with killing or completely deactivating. However, all that "halting" requires is "suspension of activity" for however long or short a period of time as desired. Therefore, the references applied clearly meet this limitation regardless of the actual amount of ethanol contained therein, since the amount provided is effective in halting probiotic activity at least temporarily.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 4-12, 20-22, and 24-26 over Hastings et al., Niggemann, Biewenga et al. and Hermann et al. in light of support by Dunne et al. and Mercenier et al. as applied to claims above, and further in view of Reddy et al. were considered but not found persuasive.

Applicants rely on the arguments used in traversing the above rejection to also traverse this rejection without additional arguments. However, as explained above, the previous rejection stands. Therefore, the response set forth above to arguments also applies to this rejection.

Claims 4-12, 20-22, and 24-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al., Niggemann, Biewenga et al. and Hermann et al. (Euro. J. Pharm Sci, 1996) in light of support by Dunne et al. and Mercenier et al. as applied to claims above, and further in view of Reddy et al. (U.S. Patent # 6080401, 2000)

The descriptions of claims 4-10, 20-22, and 25-26 are recited in the 35 U.S.C § 103 rejection above and are applied here as well. Claims 11, 12, and 24 add the herb turmeric rhizome (aka. *curcuma longa* or Haridra) which is not taught by Hastings et al. and the above references. Regardless this would be obvious in view of the teachings of Reddy et al.

Claim 24 adds the product by process limitation that the "broth acting as a microbial culture media producing naturally-derived dihydrolipoic acid". As stated above the claim is to a composition so method steps or intended results are given little patentable weight over art that already reads on the ingredients of the composition (see M.P.E.P. § 2111.02 and 2113).

As mentioned in the reference above, Hastings et al. in view of the other references listed above renders obvious a composition that comprises at least one live probiotic organism, R-lipoic acid, DHLA, a nutritive agent and an agent to halt probiotic activity such as ethanol. However these two references do not specifically teach the addition of *curcuma longa* to their composition. This is taught by Reddy et al.

Reddy et al. teach a composition that, like Hastings et al., includes a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col 9, lines 33-44) to assist in weight loss and dieting (col 4, line 12), which is the same reason as Hastings et al. Reddy et al. also adds *Curcuma longa* to the composition (col 8, line 5) as a hepatic stimulant in a range of 10 to 100 mg per dose (Table 11). It would have been obvious to someone skilled in the art to add *Curcuma longa* to the composition of Hastings et al. since both inventions share a common goal for a composition to assist in a diet and also share common materials such as a probiotic blend (see M.P.E.P. § 2144.06).

While the art above teaches the components of the composition of claim 4 they do not teach the amounts limited by claim 12. However, M.P.E.P. § 2144.05 II states:

> Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the composition of claim 4, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the amounts listed in claim 12 are result effective variables whose ratio and concentration are a matter of routine optimization.

This rejection can be overcome with evidence of unexpected results that are commensurate with the scope of the claim for these concentrations.

Therefore claims 4-12, 20-22, and 24-26 remain obvious in view of the above references.

In summary no claims, as written, are allowed for this application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
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